

REMARKS

Reconsideration and withdrawal of the restriction requirement are respectfully requested.

Reordering of Claims for Election Restriction Requirement

The restriction requirement is considered to impose an inappropriate grouping of the claims under relevant PCT guidelines as set forth in that it fails to provide a consistent grouping of the claims that reflect a complete embodiment of the invention as claimed by the inventors. For example, the claim to a process of making the compound of General Formula I recited in Claim 1 is recited in Claim 3, whereas Claim 14 includes a method of use of the compound of General Formula I recited in Claim 1. These all encompass a single inventive grouping, that is, 1) a compound, 2) process for making the compound, and 3) an independent claim for use of that product. The inclusion in the grouping of a use of the product as a pharmaceutical compound is anticipated and permitted under the rules, including PCT Rules 13.1 and 13.2 and Annex B.

Traversal of the Restriction Requirement

It is respectfully suggested that an improper standard has been applied with respect to the restriction requirement. The correct standard for a PCT application "unity of invention" is set forth in the text of the Office Action. That is, certain groups of inventions are specifically permitted to be claimed together in one application in (i), for example, a product, an independent claim for a process for manufacturing the product and an independent claim for a use of the product. These three sets of independent claims correspond to Claims 1 (and 7), 3 and 14, respectively as reordered above.

The restriction requirement seems to imply that it is based on an indication that there is no "special technical feature" that links the products together. Applicants respectfully disagree. First the product is a chemical compound, (generally recited in Claim 1 and more specifically in

Claim 2). Claim 3 recites a process for the preparation of the same compound recited in Claim 1, and is specially designed for manufacturing (synthesizing) that product. Claim 14 is a straightforward method of use of that product for the purpose of treating the specified diseases or conditions in a patient. The product is a direct result of carrying out the process recited in Claim 3, and is specifically designed and limited to the process for manufacturing that product only. Significantly, following every process step by step, the process will only produce that claimed product. It is respectfully submitted that this meets the definition of "a process specially adapted for manufacture of said product" as set forth in Annex B Part 1 (e) of the PCT Rules. Thus, the lack of unity was improperly determined and Applicants respectfully request its reconsideration and withdrawal.

In further support of the improper application of the PCT Rules for unity of invention, Applicants submit herewith a copy of the Written Opinion of the International Preliminary Examining Authority (the European Patent Office, or EPO), Exhibit A attached hereto. The PCT Written Opinion not only has examined all the claims without instituting a lack of unity objection, but has also indicated that the majority of the claims have novelty and utility, and also that an inventive step is present for all claims. One tenet of administrative law is that a regulatory agency, in this case the EPO, is considered to have followed its regulatory rules in making a determination. Thus, the lack of a unity of invention objection should be given deference and the restriction requirement should be withdrawn, and all claims should be examined.

Even if the more rigorous USPTO standard for species restriction requirements is used, the requirement is improper. In a recent Federal Circuit opinion, the basis was again set forth on which a restriction requirement is proper under U.S. Patent Laws and Regulations:

"...The Patent Office can issue a restriction requirement if it finds that two or more inventions claimed in a patent application are "independent and distinct." 35 U.S.C. § 121 (1994). A process and apparatus (tool) for its practice can be restricted if either "the process *as claimed* can be practiced by another materially different apparatus or by hand" or "the

apparatus as claimed can be used to practice another and materially different process." Man. Pat. Examining Proc. § 806.05(e) (7th ed. 1998)....." Helifix Ltd. v. Blok-Lok Ltd., 1305 (Fed.Cir. 2000) 54 USPQ2d 1299, 1305. See also, Applied Materials Inc. v. Advanced Semiconductor Materials (Fed.Cir. 1996) 40 USPQ2d 1481.

The restriction requirement is improper because the application claims have not been shown to be independent and distinct inventions. Specifically, a form rule has been applied without any study of the similarity in the embodiments of the invention as claimed, and a statement that the compound structures, process of making and methods of use, as well as intermediaries are said to be so varied and dissimilar that they relate to different inventions. The underlying basis for this conclusory statement is that purportedly the claims would be classified in different classes, but no class/subclass definitions are set forth to allow the Applicants any clear understanding of the reasons why the requirement is being imposed. Moreover, the statement of "different inventions" simply does not meet the facts.

The two requirements for a proper restriction, that is, that the inventions of Groups I and II are both independent and distinct, fail to have been met, and the restriction requirement is respectfully suggested to be improper. Thus, lacking an independent and distinct status the compositions of the listed Groups are shown to be linked and as Claim 1 is a generic claim, upon a finding of patentability will provide the basis of allowance for the remaining dependent claims.

Thus, it is respectfully suggested that an improper standard has been applied in this restriction requirement, and reconsideration and withdrawal of the requirement are respectfully requested.

Provisional Election

Accordingly, Applicants choose modified Group 1, Claims 1-3, 7 and 14 for further prosecution in this application. For purposes of an election based on the grouping of claims set

forth in the Office Action only, Applicants provisionally elect Group I, Claims 1, 2 and 7, drawn to a compound and to a corresponding pharmaceutical composition. Applicants reserve the opportunity to file one or more divisional applications on the remaining Group claims in the future.

Further Provisional Election of Species

For purposes of election of a single species requirement, Applicants elect the following Compound, also recited in Claim 2 and described in the specification as EXAMPLE 6 on page 43 of the specification as originally filed:

(2-Methoxy-10-(4-Methylpiperazin-1-ylmethyl)-5-thia-4b-aza-indeno[2,1-a]indene-5,5-dioxide)

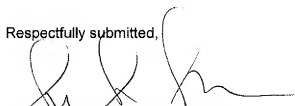
for further prosecution in this application. Applicants further rely of a showing of patentability of the generic compounds as recited in Claim 1 as support for the patentability of all non-elected species.

Petition for a One (1) Month Extension of the Response Deadline

Whereas the mail date of the of this Election/Restriction requirement was June 15, 2009, and a shortened statutory period for timely filing of a response expired one (1) month from the mailing date on July 15, 2009, the Applicant hereby seeks a one (1) month extension of the statutory response deadline, extending the deadline from July 15, 2009, up to and through August 15, 2009. Provision for payment of the extension fee is being submitted herewith in addition to the AUTHORIZATION TO PAY AND PETITION FOR ACCEPTANCE OF ANY NECESSARY FEES submitted at the beginning of the this paper to address any deficiencies or overages in fee payments.

The examiner is invited to contact the undersigned with any inquiries regarding this submission.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Sean S. Swidler', written over a horizontal line.

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Date: August 11, 2009

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EXHIBIT A

INTERNATIONAL SEARCH REPORT

Internet application No.

PCT/IN 03/00393

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 C07D513/04 A61K31/425 A61P25/00 //(C07D513/04, 275:00, 209:00)

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Main patent classification searched (classification system followed by classification symbols)

IPC 7 C07D A61K A61P

Documentation searched other than main patent classification to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

CHEM ABS Data, EPO-internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	BENINCORI T ET AL: "Chiral atropisomeric five-membered biheteroaromatic diphosphines: new ligands of the bibenzimidazole and biindole series" JOURNAL OF ORGANOMETALLIC CHEMISTRY, ELSEVIER-SEQUOIA S.A. LAUSANNE, CH, vol. 529, no. 1, 15 February 1997 (1997-02-15), pages 445-453, XP004061325 ISSN: 0022-328X compound 9	9



Further documents are listed in the continuation of box C



Parent family members are listed in annex.

* Special categories of cited documents:

A document defining the general state of the art which is not considered to be of particular relevance

E earlier document but published on or after the international filing date

L document which may throw doubts on priority claims or which is cited to establish the publication date of another citation or other special reason (see specification)

O document relating to an oral disclosure, use, exhibition or other means

P document published prior to the international filing date but later than the priority date claimed

** later document published after the international filing date or priority date and not included with the specification but cited to understand the principle or theory underlying the invention

X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

** document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

X document member of the same parent family

Date of the actual completion of the international search

23 March 2004

Date of mailing of the international search report

01/04/2004

Name and mailing address of the ISA
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INTERNATIONAL SEARCH REPORT

Internat. Application No.
PCT/IN 03/00393

C (Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Referred to claim No.
A	DATABASE CA 'Online' CHEMICAL ABSTRACTS SERVICE, COLUMBUS, OHIO, US; SHEN, JINGKANG ET AL: "Preparation of indolylpiperidines for treatment of Alzheimer's disease" retrieved from STN Database accession no. 139:6769 XP002274E54 abstract & CN 1 345 724 A (SHANGHAI PHARMACEUTICAL INST., CHINESE ACADEMY OF SCIENCES, PEOP. REP.) 24 April 2002 (2002-04-24)	1,7,14
A	WO 02 42292 A (SCIOS INC) 30 May 2002 (2002-05-30) claim 1; claim 38 (page 90, line 5, page 91, line 5, page 92, line 5, page 93, line 1; claims 42 and 44	1,7,14
A	WO 00 34242 A (VIRGINIA COMMONWEALTH UNIVERSITY) 15 June 2000 (2000-06-15) page 1, paragraph 3 -page 2, paragraph 2; claim 6	1,7,13
A	GB 2 341 549 A (MERCK SHARP & DOHME) 22 March 2000 (2000-03-22) claims 1,12	1,7,13, 14

INTERNATIONAL SEARCH REPORT

Inventor: an application No.
PCT/IN 03/00393

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☒ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
see FURTHER INFORMATION sheet PCT/ISA/210
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this International application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.2

The scope of claims 2 and 7, in as far as the expressions "the prodrug" and "its useful bio-active metabolites" is concerned, is so unclear (Article 6 PCT) that a meaningful International Search is impossible with regard to this expressions.

The applicant's attention is drawn to the fact that claims, or parts of claims, relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IN 03/00393

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
CN 1345724	A	24-04-2002	NONE
WO 0242292	A	30-05-2002	AU 2691102 A 03-06-2002 CA 2429605 A1 30-05-2002 EP 1341782 A2 10-09-2003 WO 0242292 A2 30-05-2002 US 2003092717 A1 15-05-2003
WO 0034242	A	15-06-2000	AU 767009 B2 30-10-2003 AU 2356200 A 26-06-2000 CA 2353962 A1 15-06-2000 EP 1149078 A1 31-10-2001 US 2002103382 A1 01-08-2002 US 2002103383 A1 01-08-2002 WO 0034242 A1 15-06-2000
GB 2341549	A	22-03-2000	US 6187805 B1 13-02-2001